



July 31, 2024

AnX Robotica Corp.
Tim Thomas
VP, Regulatory/Quality/Clinical
6010 W Spring Creek Parkway
Plano, Texas 75024

Re: K241934

Trade/Device Name: NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule/Tether (NaviCam Xpress Stomach System with NaviCam Capsule/Tether)

Regulation Number: 21 CFR 876.1310

Regulation Name: Magnetically Maneuvered Capsule Endoscopy System

Regulatory Class: Class II

Product Code: QKZ

Dated: June 28, 2024

Received: July 2, 2024

Dear Tim Thomas:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.

Assistant Director

DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices

OHT3: Office of Gastrorenal, ObGyn,

General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K241934

Device Name

NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule/Tether (NaviCam Xpress Stomach System with NaviCam Capsule/Tether)

Indications for Use (Describe)

The NaviCam Stomach Capsule is intended for visualization of the stomach of patients greater than or equal to 6 years old with BMI less than or equal to 65 and a waist circumference less than or equal to 77 inches. The system can be used in clinics and hospitals, including ER settings.

The NaviCam Tether is an accessory of the NaviCam Stomach Capsule. It is intended to aid the Capsule for visualizing the esophagus (not magnetically maneuvered) prior to the Capsule's release into the stomach for a stomach capsule endoscopy (MCCE) procedure.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System)
with NaviCam Stomach Capsule/Tether
510(k) Summary

510(k) SUMMARY

NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System)
with NaviCam Stomach Capsule/Tether

510(k) Number K241934

1. SUBMITTER

Applicant's Name:

AnX Robotica, Corp.
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Phone: (469) 606-9495

Primary Contact:

Tim Thomas, RAC
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Email: tim.thomas@anxrobotics.com

2. DATE PREPARED JUNE 28, 2024

3. DEVICE

Trade Name: NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule/Tether

Classification Code: **Name:** Magnetically maneuvered capsule endoscopy system
Product Code: QKZ
Regulation No: 876.1310
Class: II
Classification Panel: Gastroenterology/Urology

4. PREDICATE DEVICES

Primary – NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule/Tether (K231960).

Reference – NaviCam Small Bowel Capsule Endoscope System with NaviCam SB Capsule/Tether (K233229).

5. DEVICE DESCRIPTION

NaviCam® Stomach Capsule Endoscope Systems enable the operator to control the capsule endoscope inside the stomach. The capsule endoscope can be moved in any direction during examination. The direction and angulation of the capsule camera head can be adjusted in

NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System)
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510(k) Summary

real-time, hence realizing complete control of capsule endoscope movement and attitude during examination in the X left and right, Y forward and backward, Z up and down directions as well as rotation clockwise and counterclockwise.

The NaviCam Capsule/Tether is a single use accessory device for the NaviCam Xpress Stomach System to allow for visualization of the esophagus (not magnetically maneuvered) prior to releasing the Capsule into the stomach.

6. INDICATIONS FOR USE

The NaviCam Stomach Capsule is intended for visualization of the stomach of patients greater than or equal to 6 years old with BMI less than or equal to 65 and a waist circumference less than or equal to 77 inches. The system can be used in clinics and hospitals, including ER settings.

The NaviCam Tether is an accessory of the NaviCam Stomach Capsule. It is intended to aid the Capsule for visualizing the esophagus (not magnetically maneuvered) prior to the Capsule's release into the stomach for a stomach capsule endoscopy (MCCE) procedure.

7. SUBSTANTIAL EQUIVALENCE

Indications

The proposed indications for use of the NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule/Tether are:

The NaviCam Stomach Capsule is intended for visualization of the stomach of patients greater than or equal to 6 years old with BMI less than or equal to 65 and a waist circumference less than or equal to 77 inches. The system can be used in clinics and hospitals, including ER settings.

The NaviCam Tether is an accessory of the NaviCam Stomach Capsule. It is intended to aid the Capsule for visualizing the esophagus (not magnetically maneuvered) prior to the Capsule's release into the stomach for a stomach capsule endoscopy (MCCE) procedure.

The current indications for use of the NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Express Stomach System) with NaviCam Stomach Capsule/Tether (K23190) are as follows:

The NaviCam Stomach Capsule is intended for visualization of the stomach of patients greater than or equal to 6 years old with BMI less than or equal to 65 and a waist circumference less than or equal to 77 inches. The system can be used in clinics and hospitals, including ER settings.

The NaviCam Tether is an accessory of the NaviCam Stomach Capsule. It is intended to aid the Capsule for visualizing the esophagus (not magnetically maneuvered) prior to the Capsule's release into the stomach for a stomach capsule endoscopy (MCCE) procedure.

The indications for use are the same, no change.

Technological Characteristics

The technological characteristics of the NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule/Tether are like the existing cleared NaviCam Xpress Stomach System. The only difference is that the capsule radio transmission frequency has been changed from 2.4 GHz to 915 MHz which has a lower SAR (specific absorption rate, i.e., energy absorption rate through human body) than 2.4 GHz. The 915 MHz frequency has been cleared by FDA for the reference device, the NaviCam Small Bowel Capsule Endoscope System with NaviCam SB Capsule/Tether (K233229).

8. PERFORMANCE DATA

Software verification and validation was conducted to ensure that the NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule/Tether successfully incorporated the prior radio transmission frequency.

9. CONCLUSION

The indications for use have not changed for the NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule/Tether. The technological characteristics of the two capsules are substantially equivalent. Therefore, the NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule/Tether is substantially equivalent to the NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule/Tether. The non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.